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10/573,158	11/13/2006	Chiho Itou	288649US0PCT	6571

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OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
KAUR, GURPREET	
ART UNIT	PAPER NUMBER
1759	

NOTIFICATION DATE	DELIVERY MODE
12/23/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary	Application No.	Applicant(s)	
	10/573,158	ITOU ET AL.	
	Examiner	Art Unit	
	GURPREET KAUR	1759	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 October 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 13-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 13-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1-11 and 13-17 are pending in the application.

Claim 12 is cancelled.

Status of the Objection

2. The objection of claim 6 is withdrawn in view of applicant's amendment.

Status of the Rejection

3. The rejection of claim 14 under 35 USC 112 second paragraph is withdrawn in view of applicant's amendment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1, 3-8 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conlan et al. (U.S. Pub. No. 2001/0053537) in view of Culkin (U.S. Pat. No. 5,080,770) and Jones et al. (WO 01/53817).

Regarding claims 1 and 13, Conlan et al. teaches a system for separating biomolecules by electrophorectic separation comprising:

a first separation membrane (13, made from polyacrylamide) (see paragraph 0083);

first and second chambers (17 and 18) for adding sample constituent are disposed on either side of the membrane (see paragraph 0017 and figure 8);

two ion-permeable restriction membranes (19 and 20) disposed on the outer side of first and second chambers (see paragraph 0030 and figure 8);

buffer storage chambers (11 and 12) disposed on the outer side of ion-permeable restriction membranes (see paragraph 0013 and figure 8);

pair of electrodes (14 and 15) are disposed outside the buffer storage chambers (see paragraph 0178 and figure 8).

Conlan et al. teaches pumping means is used to move sample, buffers or fluids in the chambers (see paragraph 0078) and a means is used to provide sample in the sample chambers (see paragraph 0017), furthermore figure 8 shows the flow of buffer between the buffer storage compartments, therefore it obvious a inlet/outlet is present in the buffer storage compartments and sample chambers. Furthermore, Culkin teaches separation apparatus including chambers (18 and 20) and (92 and 94) with inlet and outlet openings (see figure 1). Therefore it would be obvious to include openings in both

sample and buffer chambers such that sample and buffer can be transferred to other chambers or to waste or recirculated (see col. 5, ll. 32-65).

Conlan and Culkin does not teach gel is supported on a porous plate and biological material bound to the gel material.

However, Jones et al. teach a thin gel for separating and detecting a target molecule wherein the gel being placed on non-conductive porous material such a mesh or mat and (see page 5, ll. 14-20) gel further includes capturing probes such as nucleic acid probes (page 6, ll. 6-18).

Therefore it would be obvious to person of ordinary skill in the art at the time of the invention to modify the Conlan gel by placing the gel on a porous material and incorporate capturing probe in the gel because the gel supported on the mesh can be relocated or moved (see Jones, page 5, ll. 14-20) and gel with capturing probe can be utilized to detect DNA as the capturing probe such as nucleic acid probes specifically bind to the nucleic acid sequence (see Jones, page 6, ll. 6-18).

5. Regarding claims 3 and 4, Conlan teaches a pumping means to move sample, buffers or fluids (see paragraph 0078), and thus it is obvious a pumping means can feed or drain solution from buffer chambers and sample chambers. Culkin also teaches two different pumps (24 and 44) for pumping buffer and sample respectively (see figure 1).

6. Regarding claim 7, Conlan teaches suitable means are used to cool the buffer solution during separation process such that no inactivation of micromolecules occurs

(see paragraph 0079), thus it is obvious buffer solution is fed at a specific temperature to prevent inactivation of micromolecules.

7. Regarding claim 8, Conlan teaches a pumping means to move sample, buffers or fluids (see paragraph 0078) wherein buffer solution is of different composition (see paragraph 0167 and example 1) and thus it is obvious the pumping means is capable being switched between different buffer solution composition since the pumping means moves sample and buffer.

8. Regarding claims 5 and 6, Culkin indicates in figure 2, both the inlet and outlet of the separation chambers have inlet formed at the lowermost position (position of the chamber where the liquid enters) of the chamber to feed the sample and outlet formed at the uppermost position (position of the chamber where the liquid exits) of the chamber for draining the sample out. Similarly the inlet and outlet ports in buffer chambers are at the lowermost and uppermost portion of the chambers.

9. Claims 2-8 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conlan et al. (U.S. Pub. No. 2001/0053537) in view of Culkin (U.S. Pat. No. 5,080,770) Tarnopolsky (U.S. Pat. No. 5,032,247), Landers et al. (U.S. Pat. No. 5,993,626) and Jones et al. (WO 01/53817).

Regarding claims 2 and 13, Conlan et al. teaches a system for separating biomolecules by electrophorectic separation comprising:

a first separation membrane (13, made from polyacrylamide) (see paragraph 0083);

first and second chambers (17 and 18) for adding sample constituent are disposed on either side of the membrane (see paragraph 0017 and figure 8);

two ion-permeable restriction membranes (19 and 20) disposed on the outer side of first and second chambers (see paragraph 0030 and figure 8);

buffer storage chambers (11 and 12) disposed on the outer side of ion-permeable restriction membranes (see paragraph 0013 and figure 8);

Conlan et al. teaches pumping means is used to move sample, buffers or fluids in the chambers (see paragraph 0078) and a means is used to provide sample in the sample chambers (see paragraph 0017), furthermore figure 8 shows the flow of buffer between the buffer storage compartments, therefore it obvious a inlet/outlet is present in the buffer storage compartments and sample chambers. Furthermore, Culkin teaches separation apparatus including chambers (18 and 20) and (92 and 94) with inlet and outlet openings (see figure 1). Therefore it would be obvious to include openings in both sample and buffer chambers such that sample and buffer can be transferred to other chambers or to waste or recirculated (see col. 5, ll. 32-65).

Conlan and Culkin does not teach gel is supported on a porous plate and biological material bound to the gel material.

However, Jones et al. teach a thin gel for separating and detecting a target molecule wherein the gel being placed on non-conductive porous material such a mesh or mat and (see page 5, ll. 14-20) gel further includes capturing probes such as nucleic acid probes (page 6, ll. 6-18).

Therefore it would be obvious to person of ordinary skill in the art at the time of the invention to modify the Conlan gel by placing the gel on a porous material and incorporate capturing probe in the gel because the gel supported on the mesh can be relocated or moved (see Jones, page 5, ll. 14-20) and gel with capturing probe can be utilized to detect DNA as the capturing probe such as nucleic acid probes specifically bind to the nucleic acid sequence (see Jones, page 6, ll. 6-18).

Conlan, Culkin and Jones do not teach buffer solutions inlet and outlet ports functioning as electrodes.

However, Tarnopolsky teaches apparatus for electrophoretic separation wherein the electrodes are placed at the inlet and outlet of the chamber such that separate inlet is not needed (see col. 8, ll. 3-10) and moreover Landers teaches capillary electrophoresis wherein the capillary inlet and outlet act as cathode and anode (see col. 2, ll. 67 over to col. 3, ll. 1-2).

Therefore, it would be obvious to one of ordinary skill in the art to modify the apparatus of Conlan such that inlet and outlet of buffer chamber have electrodes or act as electrodes as taught by Tarnopolsky or Landers because placement of electrodes in the inlet and outlet would obviate the need to make inlet and outlet in the chamber itself

as indicated in modified apparatus of Tarnopolsky (see col. 8, ll. 3-10) and inlet and outlet will act as both electrode and to move liquid in and out of the chamber.

10. Regarding claims 3 and 4, Conlan teaches a pumping means to move sample, buffers or fluids (see paragraph 0078), and thus it is obvious a pumping means can feed or drain solution from buffer chambers and sample chambers. Culkin also teaches two different pumps (24 and 44) for pumping buffer and sample respectively (see figure 1).

11. Regarding claim 7, Conlan teaches suitable means are used to cool the buffer solution during separation process such that no inactivation of micromolecules occurs (see paragraph 0079), thus it is obvious buffer solution is fed at a specific temperature to prevent inactivation of micromolecules.

12. Regarding claim 8, Conlan teaches a pumping means to move sample, buffers or fluids (see paragraph 0078) wherein buffer solution is of different composition (see paragraph 0167 and example 1) and thus it is obvious the pumping means is capable being switched between different buffer solution composition since the pumping means moves sample and buffer.

13. Regarding claims 5 and 6, Culkin indicates in figure 2, both the inlet and outlet of the separation chambers have inlet formed at the lowermost position (position of the chamber where the liquid enters) of the chamber to feed the sample and outlet formed

at the uppermost position (position of the chamber where the liquid exits) of the chamber for draining the sample out. Similarly the inlet and outlet ports in buffer chambers are at the lowermost and uppermost portion of the chambers.

14. Claims 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conlan et al. (U.S. Pub. No. 2001/0053537) in view of Culkin (U.S. Pat. No. 5,080,770) and Jones et al. (WO 01/53817).

Regarding claim 14, Conlan et al. teaches the electrophoretic separation method comprising the steps of:

feeding sample solution to sample chambers (17 and 18) and applying voltage across the pair of electrodes (see paragraph 0017). Conlan further teaches the buffer is cycled while the separation is being conducted (see paragraph 0189) using the a system comprising:

a first separation membrane (13, made from polyacrylamide) (see paragraph 0083);

first and second chambers (17 and 18) for adding sample constituent are disposed on either side of the membrane (see paragraph 0017 and figure 8);

two ion-permeable restriction membranes (19 and 20) disposed on the outer side of first and second chambers (see paragraph 0030 and figure 8);

buffer storage chambers (11 and 12) disposed on the outer side of ion-permeable restriction membranes (see paragraph 0013 and figure 8);

pair of electrodes (14 and 15) are disposed outside the buffer storage chambers (see paragraph 0178 and figure 8).

Conlan et al. teaches pumping means is used to move sample, buffers or fluids in the chambers (see paragraph 0078) and a means is used to provide sample in the sample chambers (see paragraph 0017), furthermore figure 8 shows the flow of buffer between the buffer storage compartments, therefore it obvious a inlet/outlet is present in the buffer storage compartments and sample chambers. Furthermore, Culkin teaches separation apparatus including chambers (18 and 20) and (92 and 94) with inlet and outlet openings (see figure 1). Therefore it would be obvious to include openings in both sample and buffer chambers such that sample and buffer can be transferred to other chambers or to waste or recirculated (see col. 5, ll. 32-65).

Conlan and Culkin does not teach gel is supported on a porous plate and biological material bound to the gel material.

However, Jones et al. teach a thin gel for separating and detecting a target molecule wherein the gel being placed on non-conductive porous material such a mesh or mat and (see page 5, ll. 14-20) gel further includes capturing probes such as nucleic acid probes (page 6, ll. 6-18).

Therefore it would be obvious to person of ordinary skill in the art at the time of the invention to modify the Conlan gel by placing the gel on a porous material and incorporate capturing probe in the gel because the gel supported on the mesh can be relocated or moved (see Jones, page 5, ll. 14-20) and gel with capturing probe can be

utilized to detect DNA as the capturing probe such as nucleic acid probes specifically bind to the nucleic acid sequence (see Jones, page 6, ll. 6-18).

15. Regarding claims 15 and 16, Conlan teaches buffer is cycled while the separation is being conducted (see paragraph 0189), thus buffer solution continuously fed or drained from the buffer chambers (11 and 12) by the pump (see paragraph 0078). Conlan teach the sample is fed into the sample chambers (17 or 18) by a pumping means (see paragraph 0078), thus sample is fed continuously.

16. Regarding claim 17, Culkin indicates in figure 2, both the inlet and outlet of the buffer chambers have inlet formed at the lowermost position (position of the chamber where the liquid enters) of the chamber to feed the sample and outlet formed at the uppermost position (position of the chamber where the liquid exits) of the chamber for draining the buffer out.

17. Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conlan and Culkin as applied to claims 1 and 2 above, and further in view of Liljestrand et al. (U.S. Pat. No. 6,517,777).

Regarding claims 9-11, Conlan teaches a pumping means to move sample, buffers or fluids (see paragraph 0078) wherein buffer solution is of different composition (see paragraph 0167 and example 1) and thus it is obvious the pumping means is

capable being switched between different buffer solution composition since the pumping means moves sample and buffer.

Conlan teaches selection or application of the voltage/current applied depends on the separation (see paragraph 0092). Conlan and Culkin do not teach a waveform generator and a coordination controller.

However, Liljestrand teaches an apparatus for detecting analytes wherein a waveform generator is coupled to electrodes and a controller which is coupled to waveform generator and controls the operation of the waveform and also capable of performing fluid exchange (see col. 9 ll. 11-35).

Therefore it would be obvious to person of ordinary skill in the art at the time of the invention to incorporate a waveform generator and a controller of Liljestrand with the device of Conlan because waveform generator generate waveforms of any shape thus numerous selection or application of voltage can be applied depending on the separation needed and a controller can controlled numerous operation of the device (see col. 17 ll. 13-21) to make further to make the device a compact assembly.

Response to Arguments

Applicant's arguments filed 10/11/2010 have been fully considered but they are not persuasive.

Applicant argues on page 9 that the Jones reference does not teach gel retaining layer of claim 12 which now amended into claims 1, 2 and 14. Applicant indicates that Jones teaches gel being placed on the matt and not held in through holes as claimed.

Examiner acknowledges the cited text of Jones in the rejection does not teach gel being held in the through holes of mesh; however Jones reference does teach the gel material is held in the pores or spaces of the mesh. Examiner failed to cite (Example 2 and page 25, ll. 29-31 over to page 26, ll. 1-9) of Jones reference to teach the gel material is held in pores or spaces of the mesh, Prior art reference needs to be taken as whole and Jones reference does teach in Example 2, preparing thin gel membrane wherein the polymer gel is poured into the mesh and polymer solution wick into the mesh, thus the polymerized gel is in the spaces of the mesh to make thin gel membranes (see also page 25 11. 29-31 over to page 26, ll. 1-9).

Applicant further argues that Conlan teaches separation portion is a membrane and should not be replaced by Jones teachings. Applicant did not specifically indicate why the membrane of Conlan can not be replaced, however Jones reference teaches a thin layer gel membrane used in the electrophoresis apparatus and thus it would be obvious to modify separation membrane of Conlan, which is also used in the electrophoresis apparatus, with the Jones thin layer gel membrane because Jones thin layer gel membrane is supported on/in the mesh and can be easily relocated or moved (see Jones page 5, ll. 14-20).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GURPREET KAUR whose telephone number is (571)270-7895. The examiner can normally be reached on Monday-Friday 9:00-5:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ula C. Ruddock can be reached on (571)272-1481. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/G. K./
Examiner, Art Unit 1759

/Ula C Ruddock/
Supervisory Patent Examiner, Art Unit 1795